IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

J.B.D.L. Corp., d/b/a Beckett Apothecary, et al. Plaintiffs, vs. Wyeth-Ayerst Laboratories, Inc., et al., Defendants.	)	Case No. 1:01-cv-704
CVS Meridian, Inc. and Rite Aid Corp., Plaintiffs, vs. Wyeth, Defendant.	)	Case No. 1:03-cv-781

O R D E R

I. Introduction

Plaintiff J.B.D.L. Corp., for itself and a class of direct purchasers, alleges that Defendants Wyeth and Wyeth Pharmaceuticals (collectively "Wyeth"), violated the Sherman Act. Plaintiffs CVS Meridian and Rite Aid Corporation opted out of the J.B.D.L. class, and filed a separate Sherman Act complaint. All Plaintiffs contend that they were forced to pay a supracompetitive price for Wyeth's drug Premarin because Wyeth engaged in anti-competitive and exclusionary conduct towards one of its rivals, Duramed.

The Court has studied the extensive briefs filed by all

parties in connection with Wyeth's motion for summary judgment. The Court finds that oral argument would not aid the Court in resolving the motion. The Court will grant Wyeth's motion and enter judgment in favor of Wyeth.

II. Factual Background

Wyeth manufactures Premarin. Premarin is Wyeth's trade name for its conjugated estrogen product approved for several therapeutic purposes: for treatment of vasomotor symptoms associated with menopause; treatment of vulval and vaginal atrophy; and to prevent osteoporosis, along with more specialized uses for more rare medical conditions. See Carlton Deposition, Table 1 (Doc. 135, Appendix C-1). Wyeth has manufactured and sold Premarin since 1942. No one disputes the fact that Premarin is the largest selling estrogen replacement drug (and one of the largest selling prescription medications)in the United States.

Premarin is an **estrogen** replacement drug. Estrogen replacement therapy (ERT) is typically prescribed for women without a uterus (as after a hysterectomy). Wyeth also manufactures products for use in **hormone** replacement therapy, which involves a combination of estrogen and progestin. Hormone replacement therapy (HRT) is typically prescribed for women with intact uteruses. The two categories of therapy are related but are distinct. Premarin can be used in combination with progestin in HRT. Wyeth's products PremPro and Premphase combine estrogen and progestin into one dose.

For all of the relevant time periods, several other ERT

products were available in the market. None, however, were "conjugated" estrogen products, as is Premarin. There are no generic equivalents of Premarin approved by the FDA.

Duramed[1] manufactures Cenestin, its trade name for a newer conjugated estrogen product. Duramed obtained FDA approval to market Cenestin as a branded pharmaceutical in March 1999. Duramed had originally attempted to gain FDA approval of Cenestin as a generic equivalent to Premarin, but was not successful. It is important to note that Premarin and Cenestin are not therapeutic equivalents. See, e.g., Wyeth's Exhibit B-3, an FDA "Question and Answer" sheet about Cenestin. Cenestin, unlike Premarin, is not approved for long-term use, and thus cannot be prescribed for the prevention of osteoporosis.

Wyeth kept itself well informed of Duramed's efforts to secure FDA approval for Cenestin. Indeed, much of Plaintiffs' recitation of facts in opposition to Wyeth's motion for summary judgment is devoted to a review of Wyeth's documentation of the progress of its rival through the FDA process, and Wyeth's plans to address the impact of Cenestin's entry into the marketplace. Plaintiffs repeatedly refer to Wyeth's "Premarin Preemptive Plan", dated February 11, 1999 (Class Plaintiffs Exhibit P96, Doc. 143), as the key component of Wyeth's anti-competitive conduct.

The "Plan" was a multi-faceted market strategy to maintain

[1] Duramed Pharmaceuticals was purchased by Barr Laboratories in 2001. The company will be referred to as "Duramed" in this Order.

Premarin's dominant market share. One of its stated objectives was to hold "Cenestin to less than two percent of prescription market share in 1999, approximately $20 million in assumed sales." (Id. at WYE 132253). One part of the Plan was a demonstration for retail pharmacies on the advantageous pricing of Premarin vs. Cenestin, which Wyeth estimated would be priced below the average wholesale price (AWP) of Premarin. The demonstration showed that a pharmacy filling an ERT prescription would increase its net revenue by filling the prescription with the more expensive Premarin. Another part of the Plan was to advertise and promote Premarin's clinical differences - primarily its long-term use approval - and its longer track record. And yet another part of the "Plan" presented a strategy of limiting Duramed's "contracting opportunities" with third party payors, with whom Wyeth had in place various contracts. The "value" of these contracts to the third party payors is in the rebates Wyeth was paying for sales of various Wyeth products.

Wyeth kept a close eye on its market competitors. While Plaintiffs suggest this is part of Wyeth's anti-competitive scheming, such conduct appears to be a rational part of any market seller's business planning. See, for example, Class Plaintiffs Exhibit 97 (Doc. 143), a Wyeth "Premarin Family Business Brief" from June 21, 1999, that summarizes "Competitive Activity" from Duramed's Cenestin, but also from EVISTA, Lilly's Raloxifene, and a potential new entrant called "Activelle." In fact Wyeth appears to be closely tracking the effects of the

March 1998 launch of EVISTA on its product sales; see WYE 089614 and 089621 (Class Plaintiffs Exhibit 97), showing that Premarin prescriptions actually declined (as a share of Wyeth family product sales) after EVISTA's market entry.

A. Wyeth's PBM Contracts: The record in this case fairly establishes that rebate and "access" contracts between pharmaceutical manufacturers and third party payors are a widespread industry practice. See, e.g., deposition testimony of Dr. White, chief clinical officer of HealthNet, at pp. 180-82 (Wyeth's Exhibit E-21, Doc. 135); Dept. of Health & Human Services, "Report to the President - Prescription Drug Coverage, Spending, Utilization, and Prices" (April 2000) (excerpts at Exh. B-9, Doc. 135). The "third party payors" include not only traditional HMOs or insurers, but "pharmacy benefit managers" (PBMs). In overly simplistic terms, the rise of managed care, coupled with an increasing concern among employers and insurers with rising health care costs, created the pharmacy benefit manager and the drug formulary. (Some insurers manage plan pharmacy benefits internally, while others use an independent entity. For ease of reference, the Court will refer to both of these types of arrangements simply as "PBMs".)

The Plaintiffs generally contend that Wyeth's rebate/formulary contracts with many large PBMs permitted Wyeth to illegally maintain its monopoly in the ERT market, and to raise its prices after Cenestin's entry into the marketplace. Plaintiffs and their experts argue that the synergistic effects

of Wyeth's "sole conjugated estrogen" clauses together with Wyeth's formulas for rebates to PBMs, effectively foreclosed competition from Duramed's Cenestin.

The PBM is not involved in the actual sales transaction for the pharmaceuticals it "manages." Rather, the PBM negotiates both with the pharmaceutical manufacturers and the pharmacies that actually fill the prescriptions (many of the direct purchasers here). Manufacturers contract with a PBM for favorable formulary placement, or exclusive formulary listing in a given therapeutic drug classification. Manufacturers pay for these placements with rebates and other incentive payments.

The PBM also negotiates contracts with the pharmacies that actually buy the drugs and fill the plan members' prescriptions. These contracts are price contracts. Dr. White, of HealthNet, discussed this aspect of PBM contracts. She testified that, generally, the PBM-pharmacy contracts specify a reimbursement rate composed of the drug cost and a dispensing fee. For branded drugs, the cost is generally based on the average wholesale price of the drug less a negotiated discount. Dispensing fees also vary depending on the pharmacy and geographic location. Under the type of contract terms Dr. White describes, if the average wholesale price of a drug should go up, the pharmacy's reimbursement from the PBM would also go up.

Wyeth submitted copies of its PBM contracts (Doc. 135, Exhibits H-1 through H-95). One of these contracts that the Plaintiffs analyze is with PCS Health Services, and is dated June

1996. (Plaintiffs Exhibit 92, Doc. 143) The term of this contract is thirty months, but Section 6.2.3 permits either party, with or without cause, to terminate with sixty days written notice. The contract obligates PCS to disclose to its plan sponsors all amounts Wyeth pays PCS (in rebates and other similar types of payments), while the actual distribution of those amounts is left to PCS and its plan sponsors.

Exhibit A lists the Wyeth products that are included in the PCS "Core Formulary." These include the various available dosages of Premarin. Section II states that all rebates paid under the agreement are contingent on Premarin being listed as the Core Formulary's "exclusive conjugated estrogen." The parties agreed that, in the event of a generic competitor's market entry, PCS would "consult" with Wyeth prior to placement of the generic on the formulary. (The contract also provides an "out" for both parties in the event that PCS and Wyeth could not agree on how to properly address a generic entry.)

The contract provides for "access" rebates and "market share" rebates, based on the number of prescriptions filled by PCS plan members for various Wyeth products, including Premarin. The market share rebate is defined for the "Estrogen and Estrogen/Progestin" therapeutic class as the "Premarin family" (Premarin, Prempro and Premphase tablets.) Other products for which Wyeth paid rebates include several oral contraceptives; an antidepressant (Effexor); the NSAIDs Lodine and Oruvail; an antibiotic (Suprax); a calcium channel blocker (Verelan); and a

beta-blocker (Ziac).

B. Wyeth's "Sole CE" Contract Clauses.

Wyeth attempted to include "sole conjugated estrogen" clauses, like the one in the PCS contract discussed above, in most of its PBM contracts. (Prior to Cenestin's approval by the FDA, Premarin was the **only** "conjugated estrogen" product on the market.) Wyeth's index of its PBM contracts indicates that, as of 1/1/2000, 31 out of 74 contracts contained a "sole conjugated estrogen" clause. (See Doc. 135, Exhibit H-13) By 1/1/2002, the clause was in 23 out of 60 contracts. (Of course, these numbers do not reflect the size of the PBMs and the "number of lives" each PBM represented.)

Plaintiffs recite a number of examples of Wyeth relying on its "sole CE" clause to "force" various PBMs to refuse a place for Cenestin on their formularies. Plaintiffs Exhibit 116 is an internal Wyeth memo titled "October 1999 Highlights," summarizing news and developments in many areas of Wyeth's business, including Premarin sales and marketing. Plaintiffs quote from page 3, which states in pertinent part: "A signed agreement with Duramed, which had added Cenestin to the Express Scripts formulary, was reversed by quick, concerted action between national account sales and CD&A.[2] To date, no known managed care accounts have Cenestin on formulary." The document goes on to note the creation of a "Premarin 2000 task force assigned to

[2] "National account sales" and "CD&A" are both internal Wyeth departments.

develop a strategy to counter the threat of an AB-rated generic conjugated estrogen anticipated in 2001."

Class Plaintiffs review Wyeth's negotiations concerning the contracts with several large PBMs (Prescription Solutions, Medco, Wellpoint, Advance PCS, Integrated Pharmaceutical Services, Aetna) and with Kaiser, a managed care organization that purchased directly from Wyeth for its members. (See Doc. 143, pp. 37 to 51). In each case, Plaintiffs claim that the presence of a "sole CE" clause in the Wyeth contract gave Wyeth the leverage to "threaten" these PBMs with contract cancellation, and the attendant loss of Wyeth rebates, if the PBM added Cenestin to its formulary.

C. Wyeth's Price Increases for Premarin.

Wyeth does not dispute the fact that, after Cenestin was approved by the FDA in March 1999, Wyeth raised its prices for Premarin in a series of price increases. According to Class Plaintiffs' expert Dr. Leitzinger, "For the years 1999, 2000 and 2001, Wyeth increased Premarin's price twice annually for total annual increases of 11.8%, 12.4% and 16.8%, respectively. These price increases were not the result of any increase in Premarin costs. Nor did they reflect a response by Wyeth to price increases initiated by other ERT sellers." Leitzinger Report at p. 13 (Doc. 135, Exhibit C-7). Leitzinger also claims that for 1996-1998, Wyeth's "average rate of price increase" for Premarin was 7.58%. (Leitzinger Report at p. 47) Leitzinger, Keith Leffler (expert for CVS/Rite Aid) and Stephen Schondelmeyer (an

economic pharmaceutical expert for both the Class and CVS/RiteAid) all opine that Wyeth's price increases were possible only because Wyeth successfully foreclosed Cenestin from the ERT market through the use of its illegal PBM contracts.

Wyeth uses a longer view for purposes of evaluating its Premarin pricing. Wyeth's expert Christopher James submits a table (James Exhibit 2) calculating the annual growth rate in Premarin Average Price (for the most widely prescribed 0.625 mg dose) from 1989 to 2003. James calculates the increase from 1989 to 1990 at almost 20%, while the lowest increase for that period (1992 to 1993) was only 4%. Viewed in this longer-term fashion, Wyeth contends that its post-1998 price increases are not out of the ordinary.

D. Wyeth's Market Share

As initially noted above, Premarin has been on the market since 1942 and has had a majority market share for decades. In 1998, Premarin's overall ERT market share was 75.3%. Based on IMS data (a national source cited by all parties that provides statistical information on drug costs and utilization), Premarin's share of the oral ERT market declined in the period 1998 to 2003. In 1999, Premarin's share was 73.9%; by June 2003, its share was 68.6%. The fastest growing drug in the oral ERT market during that same time was estradiol, which grew its share from 9.4% in 1998 to 18.5% by June 2003. (See Exhibit B-11, Doc. 135).

E. The Women's Health Initiative Study

In June 2002, the Womens' Health Initiative study released preliminary results of its long-term HRT study. (See generally, the WHI website at http://www.nhlbi.nih.gov/whi.) The WHI announced its intention to prematurely stop its study of the long-term use of HRT. The WHI found that the overall risks of HRT outweighed the benefits. WHI found that HRT increased the risk of breast cancer, heart disease, stroke, and blood clots. This announcement negatively impacted sales of both HRT and ERT products (although the estrogen-only WHI study continued after June 2002). The Court agrees with Dr. Leitzinger and Dr. James, who both believe that the WHI announcement impacted the ERT market in such a major way that market behavior after that date cannot be relied on for purposes of analyzing liability or damages in this case.

III. Procedural Background of This Litiation.

In September 2000, approximately fifteen months after Cenestin was first commercially available on the market, Duramed sued Wyeth in this district, alleging that Wyeth's contracts with PBMs violated the antitrust statutes.[3] This Court denied Wyeth's initial motion to dismiss Duramed's complaint, but that case settled prior to any dispositive rulings or a trial on the merits.

J.B.D.L.'s complaint in this case, filed in October 2001, alleged that Wyeth's contracts and its post-1998 price increases

[3] See Case No. 1:00-cv-735.

violated Sections 1 and 2 of the Sherman Act.[4] This Court certified a direct purchaser class under F.R.C.P. 23 (Doc. 54, Order of May 12, 2003). The class, represented by J.B.D.L., includes both wholesalers and retail pharmacies who purchase directly from Wyeth. The class does not include the insurers, managed care organizations and pharmacy benefit managers who entered into the challenged rebate contracts with Wyeth.

Plaintiffs CVS and RiteAid, two retail pharmacies, opted out of the J.B.D.L. class and filed a separate Sherman Act complaint; their action has been consolidated with the Class Plaintiffs' action. After extensive discovery, Wyeth moved for summary judgment against Class Plaintiffs and CVS/RiteAid (Doc. 135). Class Plaintiffs (Doc. 143) and CVS/RiteAid (Doc. 144) filed lengthy opposition briefs, to which Wyeth replied (Doc. 155). Class Plaintiffs and CVS/RiteAid have sought leave to file sur-replies (Doc. 159 and 160), which Wyeth opposes (Doc. 164). Wyeth's motion has been exhaustively briefed and is ripe for decision.

ANALYSIS

I. Summary Judgment Standards

The standards for summary judgment are well established. Summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with

[4] Case No. 1:01-cv-745, McHugh Pharmacy Wynnewood, Inc. V. Wyeth-Ayerst Laboratories, Inc., was consolidated with this case, and the J.B.D.L. complaint is the operative complaint for both actions.

the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c). The party opposing a properly supported summary judgment motion "'may not rest upon the mere allegations or denials of his pleading, but ... must set forth specific facts showing that there is a genuine issue for trial.'" Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986) (quoting First Nat'l Bank of Arizona v. Cities Serv. Co., 391 U.S. 253 (1968)). The Court is not duty bound to search the entire record in an effort to establish a lack of material facts. Guarino v. Brookfield Township Trs., 980 F.2d 399, 404 (6th Cir. 1992); InterRoyal Corp. v. Sponseller, 889 F.2d 108, 111 (6th Cir. 1989), cert. den., Superior Roll Forming Co. v. InterRoyal Corp., 494 U.S. 1091 (1990). Rather, the burden is on the non-moving party to "present affirmative evidence to defeat a properly supported motion for summary judgment...," Street v. J.C. Bradford & Co., 886 F.2d 1472, 1479-80 (6th Cir. 1989), and to designate specific facts in dispute. Anderson, 477 U.S. at 250. The non-moving party "must do more than simply show that there is some metaphysical doubt as to the material facts." Matsushita Electric Industries Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). The court construes the evidence presented in the light most favorable to the non-movant and draws all justifiable inferences in the non-movant's favor. United States

v. Diebold Inc., 369 U.S. 654, 655 (1962).

The court's function is not to weigh the evidence and determine the truth of the matter, but to determine whether there is a genuine issue for trial. Anderson, 477 U.S. at 249. The court must assess "whether there is the need for trial — whether, in other words, there are any genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party." Id. at 250. "If the evidence is merely colorable, . . . , or is not significantly probative, . . . , the court may grant judgment." Anderson, 477 U.S. at 249-50 (citations omitted). The Supreme Court has held:

> The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff. The judge's inquiry, therefore, unavoidably asks whether reasonable jurors could find by a preponderance of the evidence that the plaintiff is entitled to a verdict...

Id. at 252. Hence the "'mere possibility'" of a factual dispute will not suffice. Mitchell v. Toledo Hospital, 964 F.2d 577, 582 (6th Cir. 1992), quoting Gregg v. Allen-Bradley Co., 801 F.2d 859, 863 (6th Cir. 1986).

Summary judgment is not appropriate simply because the weight of the evidence favors the moving party. Poller v. Columbia Broadcasting Systems, Inc., 368 U.S. 464, 472 (1962). The issue of material fact required "to entitle a party to

proceed to trial is not required to be resolved conclusively in favor of the party asserting its existence; rather, all that is required is that sufficient evidence supporting the claimed factual dispute be shown to require a jury or judge to resolve the parties' differing versions of the truth at trial." Cities Serv. Co., supra, 391 U.S. at 288-89.

Although summary judgment must be used with extreme caution since it operates to deny a litigant his day in court, Smith v. Hudson, 600 F.2d 60, 63 (6th Cir. 1979), cert. dismissed, 444 U.S. 986 (1979), the United States Supreme Court has stated that the "[s]ummary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed to 'secure the just, speedy and inexpensive determination of every action.'" Celotex Corp. v. Catrett, 477 U.S. 317, 327 (1986) (citations omitted).

II. Antitrust Analysis

A. Class Plaintiffs' Claim Under Section 1 of the Sherman Act.

Class Plaintiffs (but not CVS/RiteAid) assert that Wyeth's PBM contracts are illegal "exclusive dealing" contracts that substantially foreclosed competition in the relevant market, and thus violate Section 1. Wyeth seeks summary judgment on this claim, arguing that its conduct does not violate Section 1 as a matter of law.

Wyeth argues that its PBM contracts are not "exclusive dealing" contracts because those contracts do not forbid placement of alternate ERT products on the formularies of the contracting PBMs. Nor do the contracts forbid PBMs from purchasing or reimbursing their members' purchases of competing ERT products, including Cenestin. Wyeth describes its contracts as "mere preferential treatment of one product over another" rather than exclusive dealing.

Wyeth also argues that its PBM contracts did not substantially foreclose competition in the relevant ERT market. Wyeth argues that the contracts' short termination notice provisions (30 to 60 days) prevent the contracts from being characterized as illegal exclusive dealings as a matter of law. Wyeth also attacks the market foreclosure rates calculated by Plaintiffs' experts as fatally flawed, as they fail to properly account for Cenestin's availability on many of the "open" PBM formularies and in the non-PBM cash market. Wyeth claims that once properly reduced, the rates are simply too low to create a triable issue concerning an "unreasonable" foreclosure rate.

Section 1 prohibits contracts or agreements that **unreasonably** restrain trade or commerce. The contracts at issue in this case are evaluated under the "rule of reason" test. See generally, State Oil Co. v. Khan, 522 U.S. 3, 10 (1997). This analysis must take into account a variety of factors, "including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's

history, nature, and effect." Id. at 10. The first, and critical, step in any rule of reason analysis is that the plaintiff must prove that "the challenged action has had an actual adverse effect on competition as a whole in the relevant market." K.M.B. Warehouse Distributors, Inc. v. Walker Mfg. Co., 61 F.3d 123, 127 (2d Cir. 1995) (citation omitted). See also, PSI Repair Services, Inc. v. Honeywell, Inc., 104 F.3d 811, 815 n. 12 (6th Cir. 1997) ["Under the rule-of-reason analysis, the antitrust plaintiff must show, inter alia, an adverse effect on competition."]

The key questions at this juncture are (1) the appropriate definition of the relevant market, and (2) whether Wyeth's PBM contracts had an "actual adverse effect on competition as a whole" in that relevant market (or, in exclusive dealing parlance, whether the contracts substantially foreclosed competition in that market).

Relevant Market: Class Plaintiffs' expert Jeffrey Leitzinger defines the relevant product market as oral ERT products. According to Leitzinger, competing products to Premarin include Cenestin, Estratab/Menest (esterefied estrogens), Estrace/Gynodiol (micronized estradiol), Ogen/Ortho-Est (estropipate), and Estinyl (ethinyl estradiol), as well as generic versions of several of these drugs, including estradiol. (See Leitzinger Report at p. 6, n.4 and pp. 9-12.) The relevant geographical market is the United States. Wyeth's motion does not take a definitive position on the relevant market, but

concedes that it is "at least" the market for oral ERT products.

The definition of the relevant market can be a complex and difficult issue. In this case, it may well be that the relevant market is broader than just the oral ERT therapeutic category. However, Plaintiffs have put forward an acceptable definition and the reasons for it, and Wyeth does not seriously challenge this definition. For purposes of ruling on Wyeth's motion, the Court will accept Plaintiffs' definition for purposes of analyzing Class Plaintiffs' claim.

Premarin's Market Power: The record establishes (and Wyeth does not dispute) that Premarin has always had a dominant share of the oral ERT market. But majority or dominant market share does not equal "market power." It must be shown that Wyeth's large market share translated to market power that enabled Wyeth to foreclose competition in that market.

Actual Market Foreclosure: The record in this case establishes that pharmaceutical manufacturers value advantageous formulary placement. It is beyond dispute that Wyeth and its competitors (both in the oral ERT market and in the pharmaceutical market generally) seek favorable formulary placement from PBMs, and are willing to pay large sums to obtain those placements. This favorable treatment can include favorable access (preferred brand status or formulary "tier" placement), favorable pricing (rebates to PBMs and lower co-pays to PBM members), or both. Wyeth's contract with PCS (discussed above) provided for rebates not only on Premarin, but a number of other

drugs.

These formulary arrangements can be pro-competitive, as the CVS/RiteAid expert Keith Leffler admits. Rebates effectively lower the cost paid for the product by the plan sponsor. PBM rebates, when passed on to the plan sponsor, lower the sponsor's cost of providing the benefit.

It is undisputed that many of Wyeth's PBM rebate contracts also contained "sole conjugated estrogen" clauses, which in operation did not permit those PBMs to include Cenestin, approved as a "conjugated estrogen," on the formulary. If the PBM did so, it risked contract cancellation and loss of Wyeth rebates. But it is also quite clear that these clauses did not prevent PBMs from listing **other** oral ERT products (products that are not "conjugated estrogens") on their formularies. And, Wyeth submits evidence from Duramed's own documents that "open" formularies (during the period 1999 to June 2002, at least) were more prevalent than Class Plaintiffs wish to recognize. Under "open" formularies without the exclusivity clause, Premarin would not have a preferred status over Cenestin, and the co-pay for Cenestin and Premarin would be equal. Duramed itself analyzed its status with PCS, where (according to Duramed) Cenestin was available at the same copay level for at least 90% of PCS business, or over 45 million lives. Duramed notes that Cenestin's low market share at PCS (approximately 1%) was reflective of its national market conditions. Duramed concluded that "considering the fact that the overwhelming majority of PCS

business is open, with no restrictions on Cenestin," low market share simply demonstrated the need to **help drive formulary decisions by increased efforts with its field sales force.** See, DUR 010716 (Exhibit G-4, Doc. 135). To similar effect is Duramed's 8/5/99 "Update" on Cenestin, where Duramed concludes it can take a "conservative approach with regards to managed care contracting, because over 70% of managed care lives are enrolled in open formularies, meaning the majority of scripts go through with no issues and because we provide a 30 day sample." (DUR 010916, Wyeth's Exh G-5) Duramed's calculations as of 12/15/00 for the number of "lives" covered by HMOs and PBMs with access to open formularies shows that HMO open lives were 73,359,394, 85% of the identified HMOs with a total of 113,078,707 covered lives. For thirteen PBMs, covering 222,000,000 lives, the open formulary lives were 137,800,000 or 62%. (DUR010961-966, Exhibit G-6, Doc. 135)

It has often been noted that exclusivity provisions in contracts can serve useful, pro-competitive purposes. See, e.g., Jefferson Parish Hosp. Dist. No. 2. v. Hyde, 466 U.S. 2, 95 (1989) (O'Connor, J., concurring). It is only when such provisions cross the line into the arena of exclusive dealing that substantially and negatively affects market competition, that the antitrust statutes come into play.

In U.S. v. Microsoft, 253 F.3d 34 (D.C. Cir 2001), the Court of Appeals discussed the trial court's conclusion that Microsoft's "exclusive dealing" contracts with internet access

and service providers ("IAPs") did not violate Section 1. Under the terms of Microsoft's contracts, Microsoft licensed its Internet Explorer browser and an IE "access kit" to hundreds of IAPs at no cost. Microsoft then entered into rebate contracts with, or made outright payments to, the ten "most important" IAPs (such as AOL) to promote IE and "exile" Microsoft's largest browser competitor, Netscape Navigator. "Under that agreement Microsoft puts the AOL icon in the OLS folder on the Windows desktop and AOL does not promote any non-Microsoft browser, nor provide software using any non-Microsoft browser except at the customer's request, and even then AOL will not supply more than 15% of its subscribers with a browser other than IE." Id. at 68.

The Microsoft district court, in analyzing the § 1 claim, concluded that "unless the evidence demonstrates that Microsoft's agreements excluded Netscape altogether from access to roughly forty percent of the browser market, the Court should decline to find such agreements in violation of § 1." This was true even though Microsoft had substantially excluded Netscape from "the most efficient channels for Navigator to achieve browser usage share," e.g., the internet access providers like AOL.

Similarly, in the recent Third Circuit case of United States v. Dentsply, 2005 U.S. App. LEXIS 3219 (Feb. 24, 2005), the district court found that Dentsply's exclusive dealer contracts did not violate Section 1, because Dentsply's actions had not foreclosed competitors from "gaining a foothold in the market." Id. at *7 (quoting from U.S. v. Dentsply, 277 F.Supp.2d 387, 453

(D. Del. 2003)). This was so even though the challenged dealer contracts prohibited Dentsply's authorized dealers from selling **any** competitor's products.[5]

This Court agrees with the analysis of the district courts in both Microsoft and Dentsply. The Plaintiffs must establish that Wyeth's conduct **substantially** foreclosed actual competition in the relevant market, oral ERT products. While favorable PBM formulary placement is no doubt an effective method for sales of a drug, it is clearly not the only route Duramed had to sell its new product Cenestin. The Court cannot conclude that Wyeth's favorable or exclusive formulary placement for Premarin in many PBMs equates to actionable market foreclosure.

The parties disagree about the appropriate basis for calculation of a foreclosure rate. For instance, Leitzinger opines that 42% of Premarin sales in fourth quarter 1999 were through PBMs with "sole CE" clauses, which he concludes is substantial market foreclosure. (Leitzinger Report pp. 39-40) But, as Wyeth points out, Leitzinger fails to account for the fact that many PBMs would reimburse for a Cenestin prescription even though it was not a "favored" drug and listed on the PBM's formulary. The Duramed documents discussed above show that Cenestin did have access, even if it may not have had the best or most preferred formulary position vis-a-vis Premarin. Leitzinger also assumes that his calculated 42% foreclosure rate, based on

[5] The district court rulings on Section 1 claims were not appealed in either Microsoft or Dentsply.

4th quarter 1999 data only a few months after Cenestin was actually available on the market, should hold for the entire time period at issue. This assumption is faulty, given the volume of information in the record about changing market conditions, including Duramed's activities to try to increase Cenestin's market share. His assumption also ignores the fact that most formularies have a "waiting period" during which new drugs are evaluated for addition to a PBM's formulary. Dr. White, of HealthNet, testified that a six-month period for review prior to placement is typical. Most importantly, however, Class Plaintiffs assume that because Cenestin could not gain full or complete access to all PBM formularies in the year it entered the market, that "competition in general" was harmed as a result. The fact that other oral ERT products were not only available but were simply not impacted by Wyeth's "sole CE" contract clauses, belies such an assumption.

The Court need not resolve the dispute about the specific, appropriate foreclosure rate, because the Court finds that Class Plaintiffs have simply not established actual market foreclosure. The Court will therefore grant summary judgment to Wyeth on Class Plaintiffs' Section 1 claim.

B. Section 2 Monopolization Claim.

Class Plaintiffs and CVS/RiteAid allege that Wyeth violated Section 2 of the Sherman Act. A claim under Section 2 requires proof of two elements: (1) the possession of monopoly power in a relevant market; and (2) the willful acquisition, maintenance, or

use of that power by anti-competitive or exclusionary means as opposed to 'growth or development resulting from a superior product, business acumen, or historic accident." Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 595-96 (1985); Conwood Co. v. U.S. Tobacco Company, 290 F.3d 768, 782 (6th Cir. 2002). "Monopoly power" for purposes of section 2 can be "something greater than market power under section 1." Eastman Kodak Co. v. Image Technical Servs., Inc., 504 U.S. 451, 481 (1992).

Wyeth concedes its "monopoly power" solely for purposes of its summary judgment motion.[6] And, as noted above, Wyeth apparently concedes (at least for summary judgment purposes) that the relevant market is oral ERT products.

Wyeth argues that despite its conceded monopoly power, its PBM contracts are in fact pro-competitive and are a hallmark of competition in the pharmaceutical industry. Wyeth claims that its rebates formulas are just pricing systems, which are not actionable by the direct purchaser plaintiffs under Section 2, absent predatory pricing. Since Wyeth's prices are clearly not "predatory" (in the classic sense of below-cost pricing to squeeze out a competitor), Wyeth argues that Plaintiffs have no viable Section 2 claim.

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[6] The Court recognizes that absent Wyeth's concession on this point, a careful analysis of the existence of monopoly power is required. See generally, ReMax International v. Realty One, 175 F.3d 995, 1018-1019 (6th Cir. 1999). The Court also acknowledges that its concession will not prohibit Wyeth from challenging plaintiffs' allegation of its monopoly power in the event of a trial in this case.

Initially, the Court rejects Wyeth's somewhat simplistic argument that its lack of predatory pricing mandates dismissal of the Section 2 claims. Plaintiffs' essential allegation is that Wyeth's contracts (rebate structure plus sole CE clauses) prevented Cenestin from becoming a competitive threat, and thus allowed Wyeth to unlawfully raise its Premarin prices after Cenestin's introduction. Moreover, the Supreme Court has acknowledged the viability of Section 2 claims brought by a **competitor** that go beyond allegations of predatory pricing. See, Aspen Highlands, supra, and Kodak, supra.[7] Thus it is not **solely** the Wyeth rebates that Plaintiffs attack.[8]

Wyeth relies heavily on NWS Michigan v. General Wine & Liquor, 58 Fed. Appx. 127 (6th Cir. 2003), an unpublished decision which held that a liquor distributor lacked antitrust standing to sue its larger competitor when it failed to allege predatory pricing. The Court of Appeals held that "Whether or not General Wine's pricing mechanism violated state law, the prices themselves simply reflect the storage and transportation efficiencies available to General Wine by virtue of its

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[7] The Supreme Court subsequently described Aspen Skiing as "at or near the outer boundary of §2 liability." Verizon Communications v. Law Offices of Curtis V. Trinko, 540 U.S. 398, 409 (2004).

[8] The CVS/RiteAid expert Keith Leffler admitted in his deposition that the "more significant thing" in his analysis was the market share rebate, rather than the "sole CE" clause. See Leffler Deposition at p. 163-164. The Court does not view this testimony as limiting the CVS/RiteAid claim to Wyeth's rebate clauses, as Wyeth suggests.

privileged status." That privileged status was conferred by an explicit legislative "grandfather" clause, permitting General Wine to deal in a wider market than NWS was able to do, thus achieving economies of scale denied to NWS.

The facts of that case do not "fit" the facts here. Nor does the Court view the case as supporting the sweeping proposition which Wyeth ascribes to it (e.g., no "rebate" program can be challenged absent predatory pricing). Moreover, the Sixth Circuit has often instructed that Section 2 requires "a thorough analysis of each fact situation" in order to determine whether or not the monopolist's conduct is unreasonably anti-competitive and thus unlawful. See Conwood, supra, 290 F.3d at 782 (quoting Byars v. Bluff City News Co., 609 F.2d 843, 860 (6th Cir. 1979)). The critical questions presented here are whether Plaintiffs have established a material factual dispute as to whether Wyeth willfully maintained its historic (and apparently legally obtained) monopoly power by unreasonable anti-competitive or exclusionary means, and if so whether the Plaintiffs suffered an antitrust injury as a result.

Unreasonable Anti-Competitive Conduct

Areeda & Hovenkamp describe unlawful exclusionary conduct as acts that "are reasonably capable of creating, enlarging or prolonging monopoly power by impairing the opportunities of rivals" and that either "do not benefit consumers at all," are "unnecessary for the particular consumer benefits that the acts produce," or "produce harms disproportionate to the resulting

benefits." Antitrust Law P 749, at 141 (Supp. 2003), as quoted in "Comment: LePage's v. 3M: An Antitrust Analysis of Loyalty Rebates", 79 N.Y.U.L. Rev. 1605 (October 2004).

And it must be kept in mind, when considering an allegation of exclusionary or anti-competitive conduct, that the antitrust laws are intended to protect competition, not a competitor. See, Richter Concrete Corp. v. Hilltop Concrete Corp., 691 F.2d 818, 823 (6th Cir. 1982) ["Anticompetitive conduct is conduct designed to destroy competition, not just to eliminate a competitor."] Plaintiffs and their experts repeatedly assert that Wyeth's "sole CE" clause - which impacted only one competitor, Duramed - together with Wyeth's rebates formulas harmed "competition" in general. But there is little, if any, analysis of the effects of the challenged conduct on overall competition in the oral ERT market.

Despite this lack, Plaintiffs repeatedly point to Wyeth's expressed desire (as reflected in its "Premarin Plan" and various marketing documents in the record) to limit Cenestin's market share. But undisputed evidence that a manufacturer desires or intends to maintain or increase its product's market share at the expense of a new competitor, does not by itself create a triable issue of whether Wyeth's chosen means to achieve that desire violated the Sherman Act. See, e.g., Cargill, Inc. v. Monfort of Colorado, 479 U.S. 109, 116 (1986) ["The kind of competition Monfort alleges here, competition for increased market share, is not actively forbidden by the antitrust laws."]

Plaintiffs urge this Court to follow the recent Third Circuit decision in LePage's v. 3M, 324 F.3d 141 (3d Cir. 2003), and permit their Section 2 claims to proceed to trial. But LePage's is not controlling on this Court. And absent persuasive authority that the Sixth Circuit would follow LePage's and agree with its conclusions, this Court is not persuaded.

LePage's involved antitrust claims against 3M, the manufacturer of branded "Scotch" transparent tape, brought by LePage, 3M's competitor in the second-brand, or private label, transparent tape market. By 1992, LePage's had an 88% market share in the second-brand market, and 3M decided it would enter that market and compete with LePage's. 3M started offering rebate programs to various retailers, who could earn rebates on a variety of 3M products. Several specific types of rebates were offered. These included "bundled" rebates, and "tiered" rebates earned based on sales across six different 3M product lines, including lines in which LePage's did not compete. 3M also offered minimum purchase level agreements to two of the largest retail outlets for tape (Office Depot and Staples) for its branded Scotch tape relative to the second-brand or private label tape; if the retailer achieved a set "growth" factor for the second-brand sales, it could obtain higher rebates.

LePage's claimed that 3M's multi-tiered and bundled rebates "plus" the agreements with the largest retailers violated section 2, in that 3M was using its brand-name transparent (Scotch) tape monopoly to gain an unfair advantage in the second-brand, private

label market, by restricting the availability of LePage's lower-priced second-brand tapes.

The case was submitted to a jury, which found for LePage's on both its monopolization and attempted monopolization claims under § 2 of the Sherman Act. It found in 3M's favor on LePage's claims under § 1 of the Sherman Act and § 3 of the Clayton Act. The district court denied 3M's motions for judgment as a matter of law and for a new trial on the Section 2 claim.

On appeal, a panel of the Third Circuit reversed the District Court's judgment on LePage's § 2 claim by a divided vote. LePage's Inc. v. 3M, 277 F.3d 365 (3d Cir. 2002). However, LePage's motion for rehearing en banc was granted, and the en banc court then affirmed the trial court's decision and the jury verdict. The en banc majority essentially concluded that exclusionary conduct that used above-cost price discounting was actionable under Section 2, and upheld a verdict against 3M of approximately $68 million.

The LePage's dissent criticized the result because it erred in favor of protecting LePage's, an inefficient competitor, rather than protecting overall competition. The jury punished 3M rather severely for engaging in above-cost, discount pricing coupled with some exclusive retail contracts, an arrangement that clearly permitted 3M to increase its market share and its profits, yet did not clearly harm competition or consumers. Nor, in reality, did 3M's conduct significantly harm LePage's secondary-brand market share (which declined from 88% to 67% in

the years in which 3M's rebate programs were in effect). This latter conclusion is especially relevant, given the significant evidence in the record that LePage's market difficulties were caused by its own conduct and market decisions, and were not the result of 3M's challenged conduct.

The Third Circuit decision also leaves unclear (at least to this Court) the precise nature of 3M's violation of Section 2. The verdict imposed a heavy penalty on 3M without producing consistent guidance for what is permissible price competition in the retail market for a simple item like transparent tape. That marketplace appears far less complex than the current United States marketplace for pharmaceuticals.

In contrast to LePage's is the Eighth Circuit decision in Concord Boat Corp. v. Brunswick Corp., 207 F.3d 1039 (8th Cir. 2000), which Wyeth advocates. There, a group of power boat manufacturers sued Brunswick, the leading supplier of inboard and stern drive engines that the plaintiffs bought and used in their boats. Plaintiffs alleged that Brunswick engaged in anticompetitive conduct because it (1) began a market share discount pricing program in 1984, under which list price discounts were given for purchases of specified percentages of engine purchases made from Brunswick. Additional long term discounts could be earned for signing a market share agreement for up to three years. Volume discounts based strictly on sales quantity were also used. When one of Brunswick's largest competitors introduced a new stern drive in 1985, Brunswick

responded by purchasing two of the largest domestic boat builders (Bayliner and Sea Ray), thus vertically integrating its business.

The plaintiffs later filed suit, contending that the synergistic effect of the market share/volume discount programs, and Brunswick's willful vertical integration efforts, resulted in plaintiffs being charged supracompetitive prices for Brunswick engines, and also drove other engine manufacturers out of the market. Brunswick's summary judgment motion was denied, and after a ten week trial the jury awarded judgment for plaintiffs of over $44 million. After unsuccessful post-trial motions seeking to set aside the verdict, the final award against Brunswick was $142,165,931.12.

The Eighth Circuit reversed and remanded for entry of judgment in favor of Brunswick. Concerning plaintiffs Section 2 claim, the Circuit noted the strong line of authority that above cost discounting is not anticompetitive conduct as a matter of law and sound policy. See generally, Brooke Group Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 223 (1993). While the Eighth Circuit rejected Brunswick's suggestion that above cost pricing is always per se lawful, it also rejected plaintiffs' argument that Brunswick's discounts "plus" - in that case Brunswick's vertical integration purchases along with several other instances of allegedly anticompetitive conduct - could together result in a violation of Section 2. The Court noted that the boat builders were not required to refrain from purchasing from competitors, and were free to walk away from

Brunswick's discounts if they got a better offer. The Court rejected the plaintiffs' arguments that Brunswick's discounts created "golden handcuffs" that amounted to an impenetrable barrier to the entry of additional competitors.

The Supreme Court denied certiorari in both Concord Boat and in LePage's.

The Plaintiffs here urge that the scale is tipped in favor of their position, and the reasoning of LePage's, by two additional cases; U.S. v. Dentsply, supra, and Masimo v. Tyco Health Care Group, 2004 U.S. Dist. LEXIS 26916 (C.D. Cal. 2004). Neither of these are of substantive assistance. U.S. v. Dentsply was an action by the Justice Department, seeking only injunctive relief against Dentsply's enforcement of its truly exclusive dealing clause in its purchase order contracts. Dentsply had historically sold its products through dealers, who in turn sell to dental laboratories that fabricate the final artificial teeth or dentures that dentists (and their patients) buy. Some of Dentsply's competitors also sold directly to the laboratories, but that outlet for sales was small. Dentsply had long "discouraged" its dealers from selling products of its competitors; but in 1993, it adopted an explicit contract provision that its authorized dealers "may not add further tooth lines to their product offering." (The relationship between Dentsply and its dealers was on a purchase-order basis, which the Third Circuit characterized as "essentially terminable at will.") The district court found that the challenged contract clause did

not violate Section 2, but the Third Circuit reversed. Following LePage's, the Court found that the contract provision essentially foreclosed all competition from the market, finding that "the firm that ties up the key dealers rules the market." 2005 U.S. App. LEXIS 3219 at *20. The Court believes a key difference between Dentsply and the case at bar lies in the fact that Dentsply's contract clause barred **all competition** from the dealer network, which was how the overwhelming majority of dental products were sold into the market.

Masimo, a California district court opinion denying summary judgment on section 1 and 2 claims, involves a disparate mix of strategies adopted by the defendant, Tyco Corp., in its sales of pulse oximetry sensors and patient cables, sold to hospitals, health networks and other equipment manufacturers. The conduct included "loyalty discounts" to hospitals in exchange for agreements not to purchase more than 5 to 15% of their oximetry products from competitors; a few "sole source exclusive dealing arrangements" with hospital group purchasing organizations; offering "bundled rebates" to two of its customers which provided rebates when oximetry and non-oximetry products were purchased together; offering financing programs to hospitals that imposed penalties if the hospital switched to a competitor's oximetry products; and co-marketing contracts with original equipment manufacturers (OEMs) that required the OEMs that used Tyco's modules to also recommend that Tyco sensors be used, rather than those of Tyco's competitors, even when competitors sensors could

have been used. The district court, relying on LePage's, found that a jury could find that the combined effect of all of Tyco's conduct resulted in actionable anticompetitive conduct, and denied Tyco's summary judgment motion. This Court of course is not bound to adopt the reasoning of the California district court, and is not inclined to do so given its heavy reliance on LePage's.

Conwood v. U.S. Tobacco, supra, a Sixth Circuit decision that is binding on this court and that Plaintiffs argue supports denial of Wyeth's motion, is distinguishable. There, U.S. Tobacco ("USTC") appealed a jury verdict in favor of Conwood on its antitrust claims; Conwood and U.S. Tobacco competed in the "moist snuff" market, with USTC the largest seller. The Sixth Circuit denied USTC's appeal from both the jury verdict and the trial court's denial of its summary judgment motion, noting that there was sufficient evidence of USTC' willful anticompetitive conduct to submit the case to the jury. USTC argued that Conwood's injury (undeniable loss of market share and profits in areas where the two companies were in direct competition) flowed only from USTC's exclusive selling agreements with retailers, which were entirely legal. But the evidence in that case of USTC's conduct included not only exclusive retail agreements, but also evidence that USTC intentionally removed Conwood's package racks from retail stores without permission of store managers, and destroyed or discarded the racks, then put Conwood product cans into USTC's own racks in an attempt to "bury" Conwood's

products; trained its sales representatives to trick store representatives and clerks so that the Conwood racks and products could be moved or destroyed; and that USTC provided misleading and incorrect information about sales data for USTC and competitors' products, to encourage the retailers to stock more of USTC's products and less of the competitors products. No such tortious conduct is involved in the case before the Court.

Thus, this Court finds itself faced with somewhat imprecise and certainly conflicting standards by which to judge Plaintiffs allegations of Wyeth's monopolistic behavior. LePage's obviously favors letting a jury sort it out, using the same imprecise, conflicting Section 2 standards transformed into jury instructions. Concord Boat, on the other hand, illustrates the dangerous possibility of a tremendous waste of time and resources of all involved here in permitting a jury to "sort it out" when the appellate court may well find that there is no jury issue here.

Professor Elhauge has observed that there is a great deal of ambiguity and uncertainty in the current legal formulations of monopolization claims. He notes in particular the problem of submitting these sorts of claims to a jury: "And if the judges don't decide the issue, the same problem will infect jury verdicts, for the typical set of jury instructions . . . leaves it up to the jury to divine the metaphysical difference between acquiring or maintaining monopoly power through (1) willful, anticompetitive, or exclusionary means or purposes, and (2)

business acumen, superior products, competition on the merits, or valid and legitimate business reasons. Without more guidance, different jurors are likely to use completely different normative understandings about what all these terms mean." E. Elhauge, "Defining Better Monopolization Standards", 56 Stan. L. Rev. 253, 266-267 (Nov. 2003).

The Supreme Court noted just last year that, "Under the best of circumstances, applying the requirements of Section 2 can be difficult because the means of illicit exclusion, like the means of legitimate competition, are myriad. ... Mistaken inferences and the resulting false condemnations are especially costly, because they chill the very conduct the antitrust laws are designed to protect." Verizon Communications v. Law Offices of Curtis Trinko, LLP, 540 U.S. 398, 414 (2004) (internal citations omitted).

Based on the record before the Court, there is little doubt that Wyeth desired and intended to thwart Cenestin's market share growth with a vigorous multi-faced marketing campaign. Plaintiffs focus on one piece of that campaign, Wyeth's PBM contracts, and cry foul. But absent explicit, controlling appellate authority that Wyeth's conduct in executing those contracts, a practice that is widespread throughout the larger and unique pharmaceutical market in the U.S., runs afoul of the guiding principles of Section 2 liability, this Court believes that the approach adopted by the Eighth Circuit in Concord Boat is correct. Wyeth's pricing behavior "plus" - in this case the

"plus" factor being the "sole CE" contract clause - did not violate Section 2 of the Sherman Act. Wyeth's motion for summary judgment against the Class Plaintiffs and CVS/RiteAid on the Section 2 claims is therefore granted.

Antitrust Injury

Even if the Court were convinced that Plaintiffs' Section 2 claims survive Wyeth's motion, Plaintiffs must also establish that they have suffered an "antitrust injury" in order to proceed. The Sixth Circuit again recently noted that "antitrust standing to sue is at the center of all antitrust law and policy. It is not a mere technicality. It is the glue that cements each suit with the purposes of the antitrust laws, and prevents abuses of those laws. . . . A private plaintiff may not recover damages under the antitrust laws merely by showing an 'injury causally linked to an illegal presence in the market.' " Worldwide Sports v. NCAA, 388 F.3d 955, 964-65 (Gibbons, J. concurring) (internal citations omitted). Antitrust laws are intended to prevent injuries to **competition**, and thus provide a remedy only for those losses that stem from the competition-reducing aspects of a defendant's conduct. There must be a distinct causal link between that challenged conduct, and the harm which Plaintiffs allege they have suffered. The Sixth Circuit has been zealous in ensuring that this element of an antitrust claim is satisfied. See, e.g., Hodges v. WSM, Inc., 26 F.3d 36 (6th Cir. 1994); Valley Products v. Landmark, 128 F.3d 398 (6th Cir. 1997); and Indeck Energy Services v. Consumers Energy Co., 250 F.3d 972 (6th Cir.

2000).

In Re Cardizem CD Antitrust Litigation, 332 F.3d 896 (6th Cir. 2003) does not "lower the bar" of this requirement, as Plaintiffs suggest. Cardizem involved an interlocutory appeal from the district court's denial of the defendant's Rule 12 motion to dismiss for failure to allege antitrust injury. At issue there, as described by the Sixth Circuit, was a "plain vanilla horizontal agreement to restrain trade in the form of a multi-million dollar cash payment," paid by the defendant to a competitor in order to delay the competitor's introduction of a generic substitute for Cardizem. Id. at 914. After ruling that the agreement was per se illegal, the Sixth Circuit also held that the district court correctly denied the motion to dismiss. Here, the Rule 56 standards apply, not Rule 12. And Wyeth's PBM contracts are clearly not illegal per se.

Here, understanding the antitrust injury Plaintiffs allege requires a two-step analysis. First, Cenestin's lower market share from 1999-2002 was caused by Wyeth's PBM contracting practices. Second, once Wyeth "realized" that it was successful in keeping Cenestin at that lower market share, Wyeth willfully and illegally raised its price for Premarin.

Class Plaintiffs and CVS/RiteAid rely on their economic experts to establish the link between Wyeth's alleged exclusionary/anticompetitive conduct, and Wyeth's alleged supracompetitive price increases in the period 1999 to 2002. Leitzinger, Class Plaintiffs' expert, states that the increases

were not tied to increases in Wyeth's costs to produce and market Premarin, nor to price increases in competitors' products. He therefore concludes (Leitzinger Report at pp. 40-45) that "By limiting Cenestin's development as a competitor and by restricting share growth by other oral ERT products, Wyeth maintained its hold on customers and avoided the need for any defensive pricing reactions. This enhanced Wyeth's market power relative to that it would have enjoyed had Cenestin's entry been unconstrained."

Leitzinger packs a series of assumptions into his conclusion. His primary assumption, of course, is that it was Wyeth's PBM contracts alone that "limited Cenestin's success," not Duramed's decisions or strategies for marketing its new product, nor any of the admitted clinical differences between Cenestin and Premarin, nor any other aspects of Wyeth's strategic planning for its ERT/HRT product line.

Concerning Duramed's marketing of Cenestin, Leitzinger relies entirely upon the opinion of another of Plaintiffs' experts, Stephen Schondelmeyer, that Duramed undertook a "substantial, concerted marketing effort." (See Schondelmeyer Report, Wyeth's Exh C-11 at ¶92) Schondelmeyer, in turn, relies heavily upon testimony from Duramed and Solvay, its marketing partner, who (unsurprisingly) blame Wyeth almost exclusively for Cenestin's failure to achieve the market share Duramed desired. While an expert may rely on another expert's opinion under Rule 702, neither Leitzinger nor Schondelmeyer offer any objective

study to confirm this point. Worse, they ignore substantial evidence in the record that contradicts their assumption. They ignore the data discussed above concerning Duramed's unfettered access to "open" formularies, a fact Duramed used as a part of its own marketing strategy. They ignore the fact that a 1.25 mg. dosage of Cenestin was not approved by the FDA until March 2000, and was unavailable on the market until May 3, 2000. This is the most popular dosage level for Premarin. (See Wyeth's Exhibit B-5) PCS Health Systems told Duramed that primary resistance to listing Cenestin on formulary was Duramed's lack of this popular dose. (See Wyeth's Exhibit G-4, DUR010716)

Leitzinger also fails to note or take account of the undisputed clinical and therapeutic differences between Cenestin and Premarin. Those differences include Premarin's long history and track record of use, clinical studies, and long-term use for osteoporosis prevention. Wyeth used these differences in its "Premarin Strategy" advertising. And, PCS Health also told Duramed in June 2000 that Cenestin's lack of an osteoporosis indication would "likely result in a non-formulary status for 2001." (Wyeth's Exhibit G-4, DUR010717).

Plaintiffs' experts fail to address the fact that Premarin's nearest competitor in the oral ERT market, estradiol, actually doubled its market share from 1998 to 2003 (from 9.4% to 18.5%); Premarin's market share in the same period declined (from 75.3% to 68.6%). If "overall competition" was harmed by Wyeth's PBM contracts, this kind of growth in a competitor's market share

should, at the least, be explained or distinguished.

Also of note is Duramed's report on United Health Care ("UHC"), a large insurer with 44 regional health plans that varied widely in the type of pharmacy benefit programs offered. In 2000, UHC agreed to allow Cenestin equal co-pay status with Premarin for a plan with 650,000 covered lives; the pilot program was designed to monitor market demand. Duramed notes that "unfortunately the results were less than favorable. The Cenestin market share fell far short of the targeted 5% UHC anticipated and needed to make the addition of Cenestin 'worthwhile.'" (Wyeth Exhibit G-4, DUR 010717). Indeed, Duramed's internal "review" of its managed care relations for July 2000 concludes that lack of physician demand for Cenestin was the first-listed cause of lower managed care access, "as monitored by competitive market share in unrestrictive open markets . . .". This admission significantly weakens Leitzinger's and Schondelmeyer's assumptions about Duramed's efficient, competitive marketing for Cenestin.

To similar effect is the fact that Cenestin's sales in the cash market segment, the Medicaid segment, and in the PBM-HMO segment, were all relatively stable throughout the period. If the PBM-HMO segment of the market is so critical, one would expect to see some variation between the three different segments. Plaintiffs' experts blame this on "spill over" or "threshold effect." (See, e.g., Schondelmeyer Report, ¶131-132) This argument is that physicians will not write prescriptions for

their patients if the drug is not listed on the patients' PBM formularies, because it may cost more (through a higher co-pay) or because the physician might get a phone call from a pharmacy. But given the feedback Duramed was receiving noted above, an equally plausible explanation is that Duramed's marketing efforts were not succeeding as well as had been expected. Leitzinger does not address this possibility.

Keith Leffler, expert for CVS and RiteAid, relies on the same facts about Wyeth's PBM contracts to conclude that "Imposition and enforcement of such contractual provisions by a dominant seller with market power are clearly anticompetitive regardless of whether they are disguised as competitive responses or discounts." (Leffler Report at ¶42) But beyond this characterization of conduct, Leffler does not discuss or account for any of the other potential factors that could affect the marketplace success of a competing drug, or the specific factors that may have affected Cenestin's market share. He assumes, as does Leitzinger, that Wyeth's PBM contracts caused the Cenestin market share.

But, assuming for the moment that the cause-and-effect relationship between the PBM contracts and Cenestin's market presence is accepted, the Leitzinger and Leffler opinions on the second part of the antitrust injury analysis - that Wyeth's price increases were the result of its PBM contracts' unlawful exclusionary effects - are fatally flawed. Leffler quotes from an internal Wyeth document which states: "As market share leader

in estrogen replacement therapy, Premarin ... price increases should be aggressive to cover increasing costs and to maximize profits." (Leffler report ¶48, n. 72) From 1991 to 1998, Wyeth's average list price increase for Premarin was 6.7% per year. After 1998, the average price increase was 15.8% per year. Since Wyeth's costs were not increasing (at least at that rate), Leffler concludes that the price increases were implemented only to "maximize profits." But once again, profit maximization, even at the expense of a competitor, does not run afoul of the antitrust statutes.

But both experts opine that Wyeth "crossed the line" between legal profit maximization and illegal supracompetitive pricing. They both rely on economic theory to support this opinion. According to Leffler, basic economic theory teaches that "a seller's profit maximizing price decreases when it faces more competition." (Leffler Report, ¶47) Wyeth's price behavior doesn't fit the theory, so he concludes that it was Wyeth's monopolistic behavior that permitted it to raise its prices in the face of competition from Cenestin.

Leitzinger also relies on "basic economic theory" that a dominant seller will lower its product price in response to market entry of competitors. This economic theory, of course, in itself contains assumptions about the relevant market - in particular, cross-elastic products and equally efficient competitors. While the record is replete with references to the uniqueness of the pharmaceutical marketplace in the United

States, both Leitzinger and Leffler assume without substantive discussion that these basic pricing theories apply largely across-the-board to this unique market. There is a significant body of evidence that brand name drug prices actually rise in response to generic competition. This pricing behavior is noted in Geneva v. Barr, 386 F.3d 485, 496-500 (2d Cir. 2004), and in In re Ciprofloxacin Hydrochloride Antitrust Lit., 363 F.Supp.2d 514, 521-22 (E.D.N.Y. 2005). The Cipro court cites a July 1998 Congressional Budget Office Study concluding that prices for brand-name drugs continue to rise faster than inflation even after generic competition begins.[9] Despite this, Leitzinger and Leffler simply assume that Wyeth's pricing "should have" followed their basic theory. This Court need not accept an expert's assumption that is supported only by the "ipse dixit" of the expert. See, e.g., General Electric v. Joiner, 522 U.S. 136, 146 (1997): "But nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."

Apart from economic theory, the **factual** support for their opinions cited by both Leitzinger and Leffler consists of Wyeth's Premarin price projections. Their primary source document

[9] CBO, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry" (July 1998). A portion of this report is contained in Wyeth's Exhibit B-10, Doc. 135.

(Plaintiffs Exhibit 171, WYE180544 - 180553) is entitled "Strategic Options Summary" and is dated July 8, 1999. Its author (Wyeth marketing employee Steve Strickland) describes it as a "summary of each of the three year financial options for the Premarin Franchise. Each summary contains detailed assumptions and the net effect on sales." The summary contains a base case, an "upside - preferred" case, and a "downside" case. Each of the three options contains net sales return projections based on levels and qualities of marketing investment; several assumptions about the demographics of oral ERT use; Wyeth's ability to launch additional products in the ERT/HRT market and the timing of those product entries; and assumptions about various potential competitors, only one of which is Cenestin. (There can be no doubt that manufacturers keep close watch on competitors, and that product pricing decisions are based in part upon competitive market conditions. This is as true for pharmaceuticals as it is for Scotch tape!)

From this document, Leitzinger and Leffler conclude that the alternate assumptions about Premarin price increases are **directly** linked to the alternate assumptions about Cenestin's market performance. Thus, they both conclude that once Wyeth "knew" that it was successful in limiting Cenestin's market share through its PBM contracts, it raised Premarin list price in line with the "best case" scenario of the 1999 marketing budget projections. This is a highly questionable leap of logic. There is nothing in the document stating that the alternate scenario

price increases are tied to or dependent upon Wyeth's PBM contracts. Indeed, Leitzinger admitted that nothing in the document actually says what he believes it says, that the market share projections for Cenestin were tied to the stated price increase projections. Rather Leitzinger says he is **inferring** that "the difference in Cenestin's penetration was an important consideration distinguishing the pricing recommendations under the two cases." He also rejected the idea that **any** of the other critical assumptions contained in the document, such as quality and quantity of marketing, demographic changes, or introduction of new Wyeth products, could also affect Premarin pricing. (Leitzinger Deposition, p. 192) His refusal to recognize that distinct possibility, and his failure to attempt to control for the possibility that those other factors may have played an important role in Wyeth's price increases, makes his inference untenable.

The Court finds that Plaintiffs have not established a "but-for" causative link between Wyeth's PBM contracts and Wyeth's price increases. Therefore, Plaintiffs have not shown the existence of a triable issue of fact on whether they suffered an "antitrust injury." (The same fatal flaw exists for Plaintiffs' "but-for" damages model, which the Court need not discuss at length. Absent proof of a causative link between the alleged monopolistic conduct and the alleged supracompetitive price, the "but-for" Premarin prices offered by Leitzinger and Leffler are untenable.)

CONCLUSION

For all of the foregoing reasons, the Court will grant Wyeth's motion for summary judgment (Doc. 135) against Class Plaintiffs and intervenors CVS and Rite Aid. The motions for leave to file supplemental briefs are denied.

DATED: June 13, 2005

s/Sandra S. Beckwith
Sandra S. Beckwith, Chief Judge
United States District Court